



**Intervention vs. implementation
research – and the ‘grey’ area in
between**

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Why did we become interested in this issue of clinical intervention vs. implementation strategy

- Gill: “Discussions with a research team trialing a new clinical risk stratification tool for acute coronary syndrome”
- Christian: “I was helping two colleagues adapt the Organizational Readiness to Change Assessment (ORCA) to their implementation studies, and...”
- Ankie: “In landing a research proposal, I needed arguments for studying both a clinical intervention and implementation strategy with regards to...”
- Lars: “When teaching in implementation research courses I met many that said they were doing implementation research but their study proposals pointed (clearly) to something else ..”

Small group question

- Have you encountered this issue, distinguishing clinical intervention vs. implementation strategy, in a study or project?
- Why was it an issue?
- What were the main questions or concerns?
- For report back, write 3-5 bullet points on discussion

Example: Improving Mood-Promoting Access to Collaborative Treatment (IMPACT)

- Collaborative, stepped-care program for the treatment of late-life depression
- Has been shown to improve rates of depression treatment, reduce depressive symptoms and improve patient satisfaction (Unitzer et al 2002)

IMPACT comprises 7 key evidence-based practice components (Unitzer et al 2002)

1. Patient education about depression;
2. Measurement and proactive tracking of depression;
3. Treatment plans based on an evidence-based treatment algorithm, patient preference, treatment history, medication formularies in participating organizations, and financial and other considerations;
4. Evidence-based treatments such as antidepressant medications and psychotherapies such as behavioral activation or problem solving;
5. Adjustment of treatment plans according to clinical outcomes;
6. A depression care manager in primary care; and
7. Consultation from a team psychiatrist and primary care expert with referral, as clinically indicated, to specialized mental health services.

Importance of assessing implementation fidelity

- Failure to implement all 7 components might result in failure to improve the desired outcomes
 - E.g., maybe leaving out patient education fails to reduce depressive symptoms
- Deviations from 7 components might reflect appropriate local adaptation
 - E.g., maybe a rural primary care clinic can achieve most of the benefit w/out hiring a depression care manager

Implementation strategies for IMPACT

- To help support implementation of the model, the IMPACT investigators developed an implementation guide to promote dissemination and implementation of the IMPACT intervention

6 key components to the implementation guide (Unitzer et al 2005)

1. An overview of the model, including key components (i.e., the 7 evidence-based practice components);
2. Summary of evidence supporting the IMPACT model;
3. Links to print and broadcast media coverage and information for interested journalists;
4. A bulletin board to facilitate interaction among clinicians and organizations in implementing the model;
5. Implementation tools; and
6. Training opportunities.

Both content (clinical & implementation) important

- Clinical content: 7 key program components represent the elements that should be included in a fidelity checklist.
 - Where adaptation occurs, you want to document what changed & why
- 6 implementation strategies help potential adopters figure out how to do it.
 - These might also be evidence-based
 - It may be that adhering to the 6 components of the campaign is critically important in many or most settings.
- However, criterion for successful implementation of IMPACT is 7 IMPACT components (or appropriately adaptation), irrespective of implementation strategies

Clinical content & implementation strategies often combined

(WHO, 2009)

- World Health Organization (WHO) hand hygiene implementation guide
- Evidence-based clinical content:
 - 3 techniques: Use of gloves, washing hands w/ soap & water, use of alcohol-based handrub; and
 - 5 points in clinical care where hand hygiene needs to be performed (e.g., before and after touching a patient).

Clinical content & implementation strategies often combined

(WHO, 2009)

- Most of the implementation guide devoted to implementation strategies:
 - Step-wise action plans, educational resources & guidance on systems change,
 - Contingency plans for possible scenarios that may inhibit implementation (e.g., lack of availability of alcohol-based rubs); and
 - Evaluation tools [\[5\]](#).
- Point: each type of content address different needs, both are important, but assessment of implementation effectiveness/success is based on the former and not the latter.

What is what? Clinical intervention or implementation strategy?

- An example: Implementing shared decision-making in psychiatric services
- Study 1: A decision aid is developed and tested through a community based participatory design.
- Study 2: The decision support tool is implemented through training sessions and facilitators. Implementation process and effects of the tool are evaluated.
- Issues: 1) Is this decision support tool a clinical intervention or an implementation strategy for shared decision-making? 2) Is it important to decide which?

Small group discussion?

- Discussion questions:
 - What do you think causes the greyness?
 - How much does this relate to the robustness of the evidence? Or other factors you have encountered that influence this?
- For report back, write 3-5 bullet points on discussion
- Post to your bullet points to the wall
- Break for lunch

Summary of morning discussion

Issues	Solutions
<p>Both clinical and implementation are interventions</p> <p>Knowing what is core vs what is adaptable</p> <ul style="list-style-type: none">- fidelity issues- confusion/muddyness resulting from bundles and toolkits <p>Ill-conceived interventions: complexity, theoretical foundations, competing interests</p> <p>Different worldviews and disciplinary traditions</p> <p>Intervention-implementation is like science vs art</p> <p>It's grey because we are the only ones talking about it!</p> <p>Influence of context</p> <p>Ethical issues/approval</p>	<p>Clearer articulation/clarity of concepts</p> <p>Clarity of outcomes; linked to objectives</p> <p>Adopt hybrid designs</p> <p>Process evaluation critical</p> <p>More rigorous theory-driven designs</p> <p>Mixed clinical/implementation research teams</p> <p>Accept the messiness and confusion; be pragmatic</p> <p>Drop the Mode 1 way of thinking</p>

Clinical intervention vs. implementation strategy

- Others contemplating the same issue...
 - Editorial boards, such as Implementation Science
 - Researchers, for example Curran et al. (2012)

Effectiveness-implementation Hybrid Designs *Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact*

Geoffrey M. Curran, PhD, Mark Bauer, MD,† Brian Mittman, PhD,‡
Jeffrey M. Pyne, MD,* and Cheryl Stetler, PhD‡*

Objectives: This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a “hybrid effectiveness-implementation” typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Much has been written about the nature of health care science-to-service gaps both in general¹⁻³ and relative specifically to health promotion⁴ and numerous medical specialties.⁵⁻⁹ Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements,^{10,11} time constraints for practitioners,^{12,13} lack of decision support tools and feedback mechanisms,¹³ poorly aligned incentives,¹⁴ and a host of other organizational climate and cultural factors.^{2,15,16}

EDITORIAL

Open Access

Implementation science: a reappraisal of our journal mission and scope

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Any good clinical or health services researcher would naturally welcome research which anticipates or addresses likely future implementation issues as early as possible in the development and evaluation of clinical interventions. However, publishing earlier stage hybrid designs would detract from our mission which focuses on the implementation of interventions of demonstrated effectiveness. We are generally interested in types 2 and 3 hybrid designs with a clear justification and major element of implementation research. Therefore, we usually reject type 1 hybrid designs.

STUDY PROTOCOL

Open Access

Telephone care coordination for smokers in VA mental health clinics: protocol for a hybrid type-2 effectiveness-implementation trial

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Damschroder et al. *Implementation Science* (2015) 10:68
DOI 10.1186/s13012-015-0250-0



STUDY PROTOCOL

Implementation and evaluation of the VA DPP clinical demonstration: protocol for a multi-site non-randomized hybrid effectiveness-implementation type III trial

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Cully et al. *Implementation Science* 2012, **7**:64
<http://www.implementationscience.com/content/7/1/64>

A Hybrid Effectiveness-Implementation Trial of an Evidence-Based Exercise Intervention for Breast Cancer Survivors

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Background

The primary aims of this hybrid Type 1 effectiveness-implementation trial were to quantitatively assess whether an evidence-based exercise intervention for breast cancer survivors, Strength After Breast Cancer, was safe and effective in a new setting and to qualitatively assess barriers to implementation.



STUDY PROTOCOL

Open Access

Brief cognitive behavioral therapy in primary care: a hybrid type 2 patient-randomized effectiveness-implementation design

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The concept of hybrid designs

- Blending design components of clinical effectiveness and implementation research
- Dual focus a priori in assessing clinical effectiveness and implementation
- Could lead to:
 - More rapid translational gains
 - More effective implementation strategies
 - More useful information for decision-makers

Three hybrid types proposed ...

- 1) Testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation.
- 2) Dual testing of clinical and implementation interventions/strategies.
- 3) Testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Curran et al, Med Care 2012

Hybrid Type 1

- *“Testing a clinical intervention while gathering information on its delivery during the effectiveness trial and/or on its potential for implementation in a real-world situation”*
- Advocate process evaluation within the clinical effectiveness trial
- Produces information for use in subsequent implementation research trials

Hybrid Type 2

- *“Simultaneous testing of a clinical intervention and an implementation intervention/strategy”*
- More direct blending of clinical effectiveness and implementation research
- Note: ‘test’ of an intervention implies at least one outcome measure used and that at least one related hypothesis (however preliminary) is studied

Hybrid Type 3

- *“Testing an implementation intervention/strategy while observing/gathering information on the clinical intervention and related outcomes”*
- Useful in circumstances where:
 - There is an imperative to implement despite a lack of conclusive evidence of effectiveness
 - There is a possibility that the clinical intervention might change when implemented in a new setting or under conditions less controlled than in the effectiveness trial

Challenges to applying hybrid designs

- Different worlds of clinical & implementation researchers
 - Familiar concepts, constructs
 - Language and meaning
- Relative 'newness' of implementation science
 - Lack of expertise of grant panels, editorial boards etc.
- Hybrid studies generally more complex to execute

Examples of hybrid designs and fit with suggested approaches

	Evidence	Implementation strategy	Hybrid design type (Curran et al, 2012)
OPTION (Onset Prevention of Incontinence in Orthopaedic Nursing and rehabilitation)	+++ but for preventing UI onset?	+++ but not tested as multifaceted	2
MORal (Managers implementing Oral care evidence)	+++	+++ but not in particular context	3
PLIS (Primary Leaders Implementing Stroke evidence)	+++ but not specific	+++ but not in particular context	3

Small group discussion

- Reflecting on discussions from the morning, in what ways are the hybrid design concepts helpful or not?
- Are there other ways we should be looking at these issues? What are they?
- Where next?
- Report back: take notes & identify 1 key point from discussion

Report back

- Each group reports 1 take-home message from small group discussion
- Is there potential to develop a paper from these discussions? Open Space discussion about potential publication.

References

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